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10/588,489

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Eric Perouse

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EXAMINER

TANNER, JOCELYN C

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/588,489	Applicant(s) PEROUSE, ERIC	
	Examiner JOCELIN C. TANNER	Art Unit 4133	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 August 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/4/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This is in response to the application filed on August 4, 2006 in which claims 11-20 are presented for examination.

Status of Claims

Claims 11-20 are pending, of which 1 is in independent form. Claims 11-19 are rejected under 35 U.S.C. 102(b) and claim 20 is rejected under 35 U.S.C. 103(a).

Information Disclosure Statement

The information disclosure statement (IDS) submitted on August 4, 2006 was filed on the mailing date of the patent application on 8/04/2006. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Objections

Claim 19 is objected to because of the following informalities: The recitation "in the region of the or each clamp" contains typographical errors. Appropriate correction is required.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 11-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Berg et al (US Patent No. 6,451,048).

Regarding claim 11, Berg et al or "Berg" herein, discloses a radially deformable flexible artificial graft or "tubular prosthesis" (FIG. 2, element #30) including a frame or "lattice" (FIG. 4a, element #38) that is inherently deformable between a retracted state of small diameter and an expanded state of greater diameter due to the flexible material, i.e. nitinol, of the frame. A flexible artificial graft or "tubular prosthesis including at least two external wire connectors or "hooks" (FIG. 5, elements #34, 40 and 44) defining between them a clamp for hooking in external tissue (column 4, lines 19-21), the two hooks being carried by the lattice (FIG. 5) and due to the wire connectors being formed of the flexible material, nitinol, the wires are movable between a spaced- apart position in which the clamp is open, and a closer-together position in which the clamp is closed.

3. Regarding claim 12, Berg discloses that each wire connector or "hook" is connected to the frame or "lattice" from a connection end (FIG. 5), and the hooks of a given clamp are movable relative to each other during deformation of the prosthesis (column 6, lines 5-7) wherein the wire connectors are loaded into a sheath and radially compressed during installation.

4. Regarding claim 13, Berg discloses a frame or "lattice" including crossing wires that form meshes in the form of deformable quadrilaterals (FIG. 4a), diamond-shaped mesh having four sides, and wherein each hook (FIG. 4a, elements #34) is connected

to the lattice in a intersection or "comer" (FIG. 4a, elements #48) of a quadrilateral.

5. Regarding claim 14, Berg discloses that each wire connector or "hook" (FIG. 4a, element #34) is welded or soldered to the frame or "lattice" at its connection end (column 4, lines 65-68, FIG. 4a).

6. Regarding claim 15, Berg discloses wire connectors or "hooks" (FIG. 4a, element #34) that are extended at their connection end by a strand that is twisted around a frame or "lattice" (FIG. 4a) wherein the wire connectors are woven or twisted under and over the frame (column 5, lines 2-5).

7. Regarding claim 16, Berg discloses that each wire connector or "hook" (FIG. 5, element #40 and #44) of a given clamp presents the shape of a shepherd's crook at its hooking end (FIG. 5, element #52), The two wire connectors or "hooks" overlapping at least in part in order to form a clamp (column 4, lines 24-31) wherein the connectors protrude on both sides of the tissue to which the graft is attached, thus forming a clamp in which the extent of overlapping is dependent on the thickness of the tissue. The wire connectors or "hooks" can be curved to varying degrees to match the curvatures needed to make a graft connection (column 6, lines 35-38).

8. Regarding claim 17, Berg discloses that each wire connector or "hook" (FIG. 7a, element #34) is in the form of a substantially rectilinear blade, the two hooks extending

facing each other and spaced apart from each other when the clamp is open.

9. Regarding claim 18, Berg discloses a frame or "lattice" (FIG. 4a, element #38) is inherently elastically deformable towards its expanded position due to the flexible material, i.e. nitinol, of the frame or lattice that facilitates contraction and expansion.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berg et al (US Patent No. 6,451,048) in view of Perez et al (US Patent No. 6,984,244).

Regarding claims 19 and 20, Berg discloses all of the limitations previously discussed. It is the Examiner's position that a kit is being is interpreted as an assembly of provisions used for treating a blood vessel including a flexible artificial graft or "tubular prosthesis" (FIG. 2, element #30) wherein the frame or "lattice" (FIG. 2, element #38) is inherently deformable towards its expanded position due to the flexible material, i.e. nitinol, of the frame.

Perez et al teach a medical repair device delivery system wherein a repair device or "tubular prosthesis" is encompassed by a capsule or "holding means" (FIG. 12,

element #333) which restrains the repair device and prevents its deployment (column 12, lines 63-64). The repair device is secured by its distal end to an inner catheter or "delivery tube" (FIG. 12, element #320) which restricts the repair device from deployment and delivers the device to the treatment site. The hooks (FIG. 2, element #96) are pressed into the grooves or "channels" (FIG. 14, element #376) arranged within the stop ring or "confinement duct" (FIG. 12, element #370) attached to the distal end of the inner catheter. The capsule prevents the hooks from contacting the sheath assembly (column 12, lines 65-68, FIG. 13, element #340). The hooks are free to imbed in the vasculature once the capsule and sheath assembly are retracted (column 13, lines 12-13).

Because the devices of Berg and Perez et al teach known elements, i.e. engaging means for implantation devices, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have applied the known technique of incorporating grooves within the distal end of the sheath and to secure the wire connectors of Berg within the grooves of the sheath, as taught by Perez et al, for the predictable result of preventing the hooks from piercing the tissue prior to installation.

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Goicoechea et al (US Patent No. 6,117,167), Fan (US Patent No. 6,485,513) and Trerotola et al (US Patent No. 5,591,226) are related to implantable medical devices.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOCELIN C. TANNER whose telephone number is (571)270-5202. The examiner can normally be reached on Monday through Thursday between 9am and 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frantz Coby can be reached on 571-272-4017. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jocelin C. Tanner/
Examiner, Art Unit 4133

5/23/2008

/Frantz Coby/
Supervisory Patent Examiner
Art Unit 4133

Application/Control Number: 10/588,489
Art Unit: 4133

Page 8